1.5 Create AE

Description
This use case identifies the process whereby actors with the appropriate role authority will create a new AE Entry for a given Study Participant linked to an existing protocol.

Actors
The PI or any other designated user of *AERS* [sm] with appropriate role authority for this function.

Pre-Conditions
The actor has successfully logged into the system. The protocol has successfully been created. The Study Participant exists and has successfully been linked to an existing protocol.

Basic Course
1. The actor searches and selects a patient on which to record an AE.
2. The actor selects option to create a new AE Entry.
3. The initial data screen is presented with protocol and Study Participant identified.
4. Actor prompted to identify AE:
   - Keyword Search or PickLlist items of CTC Categories and AE Terms or MedDRA code
   - AE Detection Date (See data table and dictionary for definition)
   - AE Grade
   - Expectedness
   - Attribution
   - Hospitalization: select (**SIG: Check data elements below or is Y/N sufficient?)
     - Hospitalized
     - Extended Hospitalization
     - No

5. *AERS* [sm] searches for possible duplicate of existing AEs (See Notes business rule 5 below). No duplicate found **(^Alternate course 1.5.5 Possible Duplicate AE for Study Participant Found)**
6. Actor selects 'SAVE' button.
7. *AERS* [sm] creates unique AE Entry ID.
8. Actor is viewing a confirmation window and can choose to 'EXIT' (defaults to main menu. See Note 6 below) or 'CONTINUE DATA COLLECTION' **(see Use Case 1.6)**.

Post Conditions
After successful completion of this use case, the actor will have created an AE for a Study Participant linked to an existing Protocol.

Alternate Course 1.5.5 Possible Duplicate AE for Study Participant Found
1. AERS searches for possible duplicate. Matches on patient and data elements indicated below in business rule.

2. Notifies the actor of duplicate and displays the possible duplicate(s).
3. Actor is prompted to 'CONTINUE' the create AE function - then continues at Basic Course step 7
   or 'CANCEL' create AE function – then defaults to the main menu.

Extension Points

AERS [sm] AE Entry detail validation fails. (Detail course pending)
Actor saves and chooses to complete AE Entry at a later time.
Actor elects to input AE for investigation. AE is in "pending" state (e.g via simple narrative with email notification) until AE confirmed and data set below is completed. (**SIG: desired feature?)

Data Item

Data Item	Type	Notes/Validation Rules
AE Detection Date	Required for duplicate check	Def: date recorded in source documentation or by pt. or family caregiver.
MedDRA Code	Required if AE category and term not provided.	
CTC AE Category	Required if MedDRA Code not provided.	
AE Term	Requried if MedDRA Code not provided.	(*NOTE: Other (Specify, _____) is an AE Term for a selected Category
AE Grade	Required	
Expectedness	"Requiredness" dictated by configured institution, sponsor and protocol triggers	Timing and who of reporting dictated by configured institution, sponsor and protocol triggers
Attribution	"Requiredness" dictated by configured institution, sponsor and protocol triggers	Timing of reporting dictated by configured institution, sponsor and protocol triggers
Hospitalization	"Requiredness" dictated by configured institution, sponsor and protocol triggers	Hospitalized Extended Hospitalization No

Notes

1. Pre-existing conditions system derived from previous AE records
2. Dose Limiting toxicity derived protocol triggers; dose limiting management not covered in initial phase of AERS
3. Business rule for determining a duplicate AE: a) match on CTC AE Category and Term or MedDRA Code and if detection range is within 30 days of an existing AE.

4. If the actor chooses to ‘EXIT’ on basic Course step 9 then AERS will notify the user to complete the data collection within X?X time frame.

Risks
Pending.

Use Case dependency
13.0 User login
1.1 Create Protocol Data for AE Abstraction
1.2 Create and Link Study Participant to Protocol

Priority Assignment: TBD
1 – critical to prototype; 2 – future development; 3 – out of grant scope

1.6 AE Data Collection

Description
This use case identifies the process whereby actors with the appropriate role authority can enter additional data on an existing AE for an existing Study Participant linked to a protocol. The required data elements are dynamically created based on configured triggers and reporting needs.

Actors
Any user designated user of *AERS* sm with appropriate role authority.

Pre-Conditions
The actor has logged into *AERS* sm and has the appropriate role authority to access this function. An AE exists for an existing Study participant. The protocol has successfully been created. Notification triggers have been created. The Study Participant has successfully been linked to an existing protocol.

Basic Course
1. The actor selects option to search for AE Entries by Study Participant or Protocol.
2. *AERS* sm presents a list of AEs for editing.
3. Actor selects the interested AE.
4. AERS displays the AE data entry screen with current data.
5. Actor completes data entry.
    - Intervention (e.g. Chemotherapy – then will be prompted to enter Course #/Cycle #, Total Courses to Date during AE Use Case 1.6 data collection)
    - Study Relatedness
    - Action Outcome
    - Actor continues creating AE Entry.
    - AE Stop Date
    - Prior Therapy for Primary Disease
    - Start Date of Prior Therapy
    - End Date of Prior Therapy
    - Pre-Existing (Note: pre-filled based on prior entries)
    - Sites of Metastatic Disease
    - Concomitant Medications
6. Actor selects to save edits
7. *AERS* sm validates data detail and displays verification message.
8. *AERS* sm records timestamp and user id on successful update; audit file logged.

Post Conditions
After successful completion of this use case, the actor will have saved edits to an existing AE for a Study Participant linked to an existing protocol. Time stamp of last saved edits with User ID are readily viewable. An audit log of updates is available. Reporting Triggers may have been invoked.

Alternate Course

Pending.

Extension Points

Based on invoked triggers (pending)

Data Item

Data Item	Type	Notes/Validation Rules
AE Stop Date	Not Required	(*Issue notify for AE that is started by not stopped)
Action	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Outcome	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Prior Therapy for Primary Disease	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Start Date of Prior Therapy	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
End Date of Prior Therapy	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Pre-Existing Condition (Note: pre-filled based on prior entries)	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Sites of Metastatic Disease	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Concomitant Medications	"Requiredness" driven by reporting agencies	See reporting/routing extension use cases
Intervention	Required	CTEP: Surgery, Radiation Therapy, Drug and/or Immunotherapy, Gene Transfer, Image Directed Local Therapy, Hematopoietic Stem Cell Transplant
Course #	Required if Intervention = Drug and/or Immunotherapy	
Cycle #	Required if Intervention = Drug and/or Immunotherapy	

Notes

None identified at this time.

Risks

Pending

Use Case dependency
13.0 User login
1.1 Create Protocol Data for AE Abstraction
1.2 Create and Link Study Participant to Protocol
1.5 Create AE

Priority Assignment: TBD
1 – critical to prototype; 2 – future development; 3 – out of grant scope

1.9 Configure Institution Level AE Notification Triggers

Description
This use case will capture configuration of AE notification triggers at the institution level. An entity within an institution (e.g IRB, DSMB) will dictate the triggers for notification on all protocols regardless of type. The triggers are invoked when an AE is created and stopped when all notifications are completed (*SIG: verify if this is valid).

Actors
The System Administrator (SA) or any other designated user of *AERS* sm with appropriate SA role authority.

Pre-Conditions
The actor has identified and assigned all personnel to appropriate roles and configured email addresses or email lists for notification. The actor has successfully logged into the system.

Basic Course
1.The SA selects option to configure Institutional Level Notification Triggers.
2.AERS sm presents a Trigger Builder. The SA configures the following AE notification trigger rules or turns them 'OFF' if not applicable.

- TRIGGER CATEGORY: selects from pre-filled list or input if not found
- TRIGGER TITLE: inputs trigger title in textfield
- PROTOCOL ID: selects 'OFF' or 'ALL' or one or more protocols from key word search or ID
- SPONSOR ID: selects 'OFF' or a sponsor from key word search or ID
- GRADE: Selects equality symbol and inputs targeted grade
  - >=, >, <, <=
  - 1,2,3,4 or 5
- ATTRIBUTION: selects 'OFF' or one or more below
  - Unrelated
  - Unlikely Related
  - Possibly Related
  - Probably Related
  - Definitely Related
- EXPECTEDNESS: selects 'OFF' or one below
  - Expected
  - Unexpected
- PHASE: selects 'OFF' or one or more below
  - Pilot/Feasibility,
  - Phase I
  - Phase II
  - Phase III
  - Phase IV

- HOSPITALIZATION: selects: (**SIG: Correct data elements or Y/N sufficient?)
  - Hospitalized
  - Extended Hospitalization
  - No
- REPORT PERIOD: enter number of business days for total reporting period

3. The SA configures the notification, timing and escalation rules in the Trigger Builder:
   - Configure reporting days for protocol staff notification
     - Select the day/hrs of reporting period (e.g. If 10 day reporting period, select day 1 if notification should occur on this day)
     - Select one or more protocol staff roles.
     - Select notification method (e.g. email, pager, application notification on login)
     - Complete notification message (e.g. Subject: "IRB Reportable AE", Text: "AE created on *date and met IRB SAE reporting requirements. AE data needs completion for report generation")
     - Repeat for all interested days of reporting period, especially day just prior to reporting deadline and, optionally, x days after reporting deadline (e.g. to enter follow-up data)

   - If application should notify on login of selected staff, check box "APPLICATION NOTIFICATION ON LOGIN"

4. The SA submits selection and confirms notification rule summary.

Post Conditions
The SA has created an institution level notification trigger which includes trigger, protocol staff notification and escalation rules and entity to report to.

Alternate Course
Pending

Use Case Dependency
1.5 Create AE
1.6 AE Data Collection
1.8 Configure Protocol Staff for AE Notification
4.2 Create Report

Data Item

Data Item	Type	Validation
Trigger Title	Required	
AE Category	Not Required	
AE Term	Not Required	
Grade	Required	

Attribution	Not Required	
Expectedness	Not Required	**TBD**
Phase	Not Required	
Hospitalization	Not Required	
Report Period	Required	
Protocol Staff Roles	Required	

Notes

None identified at this time.

Risks

Pending

Use Case dependency

13.0 User login
1.1 Create Protocol Data for AE Abstraction
1.2 Create and Link Study Participant to Protocol
1.5 Create AE Entry